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Docket No.: 02994/100F606-US1
(PATENT)

15 4/13/04 Appeal Brief (3C)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Karen L. Breiges et al.

Application No.: 09/655,667 Art Unit: 3626

Filed: September 6, 2000 Examiner: Natalie Pass

For: CLINICAL TRIAL MANAGEMENT SYSTEM

APPELLANTS' BRIEF ON APPEAL UNDER 37 C.F.R. § 1.192

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In accordance with the provisions of 37 C.F.R. § 1.192, Appellant submits the following brief:

I. REAL PARTY IN INTEREST

Based on information supplied by Appellant and to the best of the Appellant's legal representative's knowledge, the real party of interest is the assignee, Schering Corporation.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences which might directly affect, or be directly affected by, or have a bearing on the Board's decision in the pending Appeal.

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III. STATUS OF CLAIMS

Pursuant to the final Office Action dated February 6, 2004:

(1) Claims 1, 6, 7, 11, 13, and 43 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Colon et al. (U.S. Patent No. 5,991,731 in view of DeBusk et al. (U.S. Patent No. 5,995,937);

(2) Claims 2-5, 15-17, 19-24, 28, 32-38, and 44 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Colon and DeBusk, as applied to claims 1, 19, and 43, and further in view of Edelson et al. (U.S. Patent No. 5,737,539);

(3) Claims 25-27, 29, 30, 42, and 45 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Colon, DeBusk, and Edelson, as applied claim 19, and further in view of Umen et al. (U.S. Patent No. 5,734,883);

(4) Claims 8-10 and 12 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Colon in view of Debusk, as applied to claim 1, and further in view of Umen;

(5) Claim 14 remains rejected under 35 U.S.C. § 103(a) as being unpatentable over Colon in view of Debusk, as applied to claim 1, and further in view of Official Notice;

(6) Claim 31 remains rejected under 35 U.S.C. § 103(a) as being unpatentable over Colon, Debusk, Edelson, and Umen, as applied to claim 25, and further in view of Official Notice; and

(7) Claims 35-38 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Thus, Claims 1-17, 19-38, and 43-45 are pending in the application, with all pending claims on appeal.

IV. STATUS OF AMENDMENTS

Responses were filed on September 8, 2003 and November 13, 2003; amendments to the claims were presented in each of the Responses. A complete set of claims as they now stand is attached as the Appendix.

V. SUMMARY OF THE INVENTION

The present invention is directed to the design of clinical trials. (Page 1, lines 5-6.) For example, claims 1-17 require a main database of information concerning prior clinical trials and resources available to conduct future clinical trials, the information on the prior clinical trials is arranged in the form of a protocol of (a) tasks to be completed, e.g., scheduled visits of a test subject, (b) measurement of prescribed physical attributes of the subject during visits, and (c) administration of a prescribed medical product to the subject during the visit to determine the subject's response. The protocol information is organized in the form of a template so the information has a similar structure and arrangement. User and main processors run a program that designs and tracks, at the user processor, a clinical trial through access by the user processor to the software template in the main database and modification of the template for formulating a new clinical trial. By accessing the template in the main database and modifying it to design a new clinical trial for use in the user processor, the new clinical trial data will be in a format comparable to the old trials. Further, the data entered into different user databases and uploaded to the main database during the subsequent clinical trial will be compatible with old data. This helps to assure that the new clinical trial will be accepted, e.g., by the FDA and where appropriate the new data can

be combined with the old data for enhanced results. Similarly, claims 19-38 and 43-44 require main and subsidiary processors to run a program that permits the design and tracking at the subsidiary user processor of a protocol of tasks to be completed for a clinical trial.

VI. ISSUES

1. Whether Claims 1, 6, 7, 11, 13, and 43 were erroneously rejected under 35 U.S.C. § 103(a) as being unpatentable over Colon et al. (U.S. Patent No. 5,991,731 in view of DeBusk et al. (U.S. Patent No. 5,995,937).

2. Whether Claims 2-5, 15-17, 19-24, 28, 32-38, and 44 were erroneously rejected under 35 U.S.C. § 103(a) as being unpatentable over Colon and DeBusk, as applied to claims 1, 19, and 43, and further in view of Edelson et al. (U.S. Patent No. 5,737,539).

3. Whether Claims 25-27, 29, 30, and 45 were erroneously rejected under 35 U.S.C. § 103(a) as being unpatentable over Colon, DeBusk, and Edelson, as applied claim 19, and further in view of Umen et al. (U.S. Patent No. 5,734,883).

4. Whether Claims 8-10 and 12 were erroneously rejected under 35 U.S.C. § 103(a) as being unpatentable over Colon in view of Debusk, as applied to claim 1, and further in view of Umen.

5. Whether Claims 35 and 36 were erroneously rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

VII. GROUPING OF CLAIMS

Appellant submits that the Claims stand and fall together in the following groupings:

- Claims 1, 6, 7, 11, 13, 14, and 43;
- Claims 2-5, 15-17, 19-24, 28, 32-38, and 44;
- Claims 25-27, 29, 30, 31, and 45; and
- Claims 8-10 and 12.

VIII. ARGUMENTS

A. All Claims: None of the applied references suggest the design of a clinical trial, let alone a clinical trial based on templates created from a protocol of tasks to be completed based on old clinical trials (Issues 1-4):

None of the applied references teaches or suggests the design of a clinical trial, as required by each of the claims. Colon relates to the conduct of an already-designed clinical trial. During the trial a doctor inputs patient data, and if the patient is eligible for the study, a study management center sends the doctor an initial suggested drug prescription. The doctor then has the option to confirm or adjust the prescription within the parameters of the clinical study protocol. The results are then sent to the host computer database for updating, and a hard copy of the drug prescription is printed.

Debusk also does not relate to the design of a clinical trial. Rather, Debusk relates to an information management system providing customized management of the use of medical resources (e.g., doctor time, equipment, and supplies) using user-configured software modules. Hospitals and health-care providers can buy an off-the-shelf software product that, through the use of the software modules, may be tailored to the facility's individuals needs. This software may be run on any stand-alone or network personal computer.

Edelson does not make up for the deficiencies of Colon and Debusk. Edelson relates to a prescription creation system, which divides a single prescription into two components for fulfillment of one portion quickly and locally at higher cost, and another portion by remote mail order at a cost savings.

Umen relates to a document production system for preparing documents and managing the composition of textual information pertaining to studies of medical products. More specifically, a computer-implemented document production system manages the composition of textual information pertaining to studies of a medical product, stores drug information within a data storage and retrieval system, and organizes the information in order to generate drug documents according to predetermined document formats.

Thus, it is clear that none of the applied references, either alone or in combination, suggests the design of a clinical trial, let alone a clinical trial based on templates created from a protocol of tasks to be completed based on old clinical trials, as required by each of the claims.

B. Claim 1: DeBusk does not teach the standardization of a prior clinical trial being stored in a database in the form of a software template (Issue 1)

Contrary to the Examiner's statement in the non-final Office Action on page 5, last paragraph, DeBusk does not teach the standardization of a prior clinical trial stored in a database in the form of a software template, as required by Claim 1. Rather, DeBusk stores modular, reusable, standard software modules that are selectable to represent a future clinical procedure to be conducted.

The Examiner responds in the final Office Action on page 11, first full paragraph, that Colon teaches the standardization of a prior clinical trial being stored in a database by it's statements of automatic assignment and randomization of thousands of participants in a clinical study "is

controlled according to scientifically developed mathematical and statistical methods" (col. 1, lines 53-54) and "consistent operation and access across all activities" (col. 7, line 67, through col. 8, line 1). Appellants disagree. Randomization of participants is not the design of the study. It does not involve scheduling visits, determining measurements or administering medications. Further, the quotes from Colon do not at all relate to the standardization of a prior clinical trial being stored in a database. And the second quote is taken from Colon out of context. The "consistent operation and access across all activities" relates to management data and other study data being stored in the same database. Thus, Claim 1 is patentable over the applied references for this additional reason.

C. Claims 6 and 7: Colon does not teach a main processor and main database in an organizational environment that includes other databases with information for formulating clinical trials (Issue 1)

Contrary to the Examiner's statement in the non-final Office Action on page 6, last paragraph, Colon does not teach a main processor and main database in an organizational environment that includes other databases with information for formulating clinical trials, as required by Claims 6 and 7. Colon has a database host computer 11 used to store study data in separate tables. Tables are joined as needed to produce databases for statistical analysis. (See Colon, col. 3, lines 14-23.) These databases do not include information for formulating clinical trials. As asserted previously, Colon relates to the conduction of an already-designed clinical trial, and thus has no need for databases with information for formulating clinical trials.

The Examiner responds on page 12, first full paragraph, of the final Office Action by stating that Colon teaches "a main processor and main database are in an organizational environment which includes other databases" with Colon's statements that "a study management center 10 ... at a particular geographical site [col. 2, lines 59-61] ... in which study data is maintained in a database

in the host computer (11) behind a firewall provided in the Internet server computer [Abstract]" First, the Examiner has pulled the two halves of this quote from completely separate portions of Colon, thereby completely misrepresenting the Colon's teachings. Second, the claims recite "a main processor and main database are in an organizational environment which includes other databases *for formulating clinical trials*" (emphasis added); Colon does not involve formulating clinical trials.

The Examiner also asserts that Colon teaches "databases with specialized information useful in formulating clinical trials," as recited in Claim 6, with Colon's statement that "tables are joined as needed to produce regional and study-level management summaries and databases for statistical analysis" (col. 3, lines 21-23). The tables in Colon include "study data for eligibility, randomization, follow-up, endpoint and management" (col. 3, line 19-20), which is data for conducting a clinical trial rather than formulating one.

Claims 6 and 7 are therefore patentable over the applied references for these additional reasons.

D. Claim 43 does not differ from claim 19 in the manner suggested by the Examiner (Issue 1)

Contrary to the Examiner's statement in the non-final Office Action in the paragraph bridging pages 7 and 8, claim 43 does not differ from claim 19 in the manner suggested by the Examiner. That is, contrary to the Examiner's statement, claim 19, like claim 43, recites that the user processor and main processor run a program permitting the design of a clinical trial in the form of a protocol of tasks to be completed and the tracking of the completion of the tasks in the protocol at the user processor. In the final Office Action the Examiner did provide a response to Appellant's assertion.

E. Claims 43 and 44: neither Colon nor DeBusk suggests the input of information with regard to completion of tasks and tracking the completion at a user processor (Issue 1)

Furthermore, neither Colon nor DeBusk suggests the input of information with regard to completion of tasks and the tracking of the completion of the tasks of a clinical trial at a user processor, as required by Claims 43 and 44. (See non-final Office Action, page 8, last paragraph.) Colon merely updates prescriptions and sends the results to a host computer database. DeBusk does not track completed tasks, not to mention at a user processor.

The Examiner responds on page 13, first full paragraph, of the final Office Action by stating that DeBusk teaches this feature with it's statement that "tracking resource utilization in individual patient cases ... [and] software allows the user to create case modules by selecting an already configured procedural pathway and adding patient and doctor specific information to it ...the user may then easily input information concerning the usage of the resources populating the clinical pathway and maintain a history of resource usage, costing information and/or clinical outcome" (col. 8, lines 29-37). However, this disclosure discusses tracking resource utilization, not task completion. The use of a resource is not the same as a clinical trial. Claims 43 and 44 are therefore patentable over the applied references for this additional reason.

F. Claims 2 and 19: Colon and DeBusk also do not suggest a program that permits the design of a clinical trial in the form of a protocol of tasks to be completed and does not track the completion of the tasks in the protocol at a user processor (Issue 2)

Colon and DeBusk also do not suggest a program that permits the design of a clinical trial in the form of a protocol of tasks to be completed and does not track the completion of the tasks in the protocol at a user processor, as required by Claims 2 and 19. As stated numerous times, the applied

references do not suggest the design of a clinical trial at all. Claims 2 and 19 are therefore patentable over the applied references for this additional reason.

G. Claims 5 and 22: Edelson does not suggest a main processor and a subsidiary processor periodically operating to synchronize replicated and changed data at the main database and the subsidiary database with changes at said main database predominating over changes at said subsidiary database (Issue 2)

Edelson does not suggest a main processor and a subsidiary processor periodically operating to synchronize replicated and changed data at the main database and the subsidiary database with changes at said main database predominating over changes at said subsidiary database, as suggested by the Examiner on page 12, second to last paragraph, of the non-final Office Action. In fact, Edelson states in column 48, lines 5-7, that each data warehouse maintains replicated copies of data sets obtained by read-only access of remote databases.

The Examiner responds on page 14, first paragraph, of the final Office Action by stating that Edelson teaches this feature by Edelson's statements that his system "preferably either synchronized or refreshed at intervals (e.g. overnight) from source databases" (col. 46, lines 49-50) as well as "[e]ach data warehouse 212 maintains replicated copies of relevant data sets obtained by *read-only access* of remote databases 210, which data sets are maintained synchronously with updated source data at remote databases 210, or are periodically refreshed therefrom, preferably at frequent intervals" (emphasis added; col. 48, lines 5-10). However, as is clear from the Examiner's quoted passages, unlike the present invention Edelson cannot synchronize replicated and changed data at the source database and the remote databases. Although the data is synchronized, it is replicated only at the source database; the data at the remote data is read-only and thus can not be replicated there. Claims 5 and 22 are therefore patentable over the applied references for this additional reason.

H. Claims 15, 16, 32, and 33: Applied references do not suggest a site management module for indicating conditions at the certain geographical location, including the portion of any protocol to be carried out in that geographical location (Issue 2)

The applied references do not suggest a site management module for indicating conditions at the certain geographical location, including the portion of any protocol to be carried out in that geographical location, as suggested by the Examiner on page 12, last paragraph, of the non-final Office Action. Colon merely discloses subjects being located at different geographic sites, and Edelson discloses looking at patient prescription activity in a limited geographical region. Claims 15, 16, 32, and 33 are therefore patentable over the applied references for this additional reason.

I. Claims 16 and 33: Neither Colon nor DeBusk suggest that information about the completion of tasks in the protocol at a certain geographical location are entered by a subsidiary user processor in a subsidiary database, and a site management module updates a portion of the protocol related thereto (Issue 2)

Contrary to the Examiner's statement on page 13, first full paragraph of the non-final Office Action, neither Colon nor DeBusk suggest that information about the completion of tasks in the protocol at a certain geographical location are entered by a subsidiary user processor in a subsidiary database, and a site management module updates a portion of the protocol related thereto, as required by Claims 16 and 33. Again, the applied references do not suggest the design of a clinical trial based on templates of an established protocol, and thus there is no updating of a protocol. Claims 16 and 33 are therefore patentable over the applied references for this additional reason.

J. Claims 17 and 34: Edelson does not suggest transferring from a main processor to a portable processor a copy of a portion of a main database related to a site for a clinical trial in a certain geographical area, the main processor locking the portion of the main database that was copied, the portable processor receiving information about the completion of tasks in the protocol at the certain geographical area and modifying the copy as a result thereof, and the portable processor transferring to and updating the main database with the modified copy of the data and unlocking that portion of the main database (Issue 2)

The Examiner states in the non-final Office Action, page 13, last paragraph, that Edelson teaches transferring from a main processor to a portable processor a copy of a portion of a main database related to a site for a clinical trial in a certain geographical area, the main processor locking the portion of the main database that was copied, the portable processor receiving information about the completion of tasks in the protocol at the certain geographical area and modifying the copy as a result thereof, and the portable processor transferring to and updating the main database with the modified copy of the data and unlocking that portion of the main database. Appellant respectfully disagrees. While access protocols are mentioned in Edelson in column 8, lines 47-50, there are no details regarding locking and unlocking portions of any databases. Claims 17 and 34 are therefore patentable over the applied references for this additional reason.

K. Claim 44: Edelson does not suggest replicating to a subsidiary database a portion of data relating to clinical trials in a certain geographical location (Issue 2)

Contrary to the Examiner's statement on page 16, fourth full paragraph of the nonfinal Office Action, Edelson does not suggest replicating to a subsidiary database a portion of data relating to clinical trials in a certain geographical location, as required by Claim 44. Rather, Edelson states in column 48, lines 5-7, that each data warehouse maintains replicated copies of data sets obtained by read-only access of remote databases.

The Examiner responds on page 15 of the final Office Action by stating that Edelson teaches this feature with Edelson's statement that data is "preferably either synchronized or refreshed at intervals (e.g. overnight) from source databases" (col. 46, lines 49-50) as well as the statement that "[e]ach data warehouse 212 maintains replicated copies of relevant data sets obtained by read-only access of remote databases 210, which data sets are maintained synchronously with updated source data at remote databases 210, or are periodically refreshed therefrom, preferably at frequent intervals" (emphasis added; col. 48, lines 5-10). However, as stated above, while the databases in Edelson are synchronized, the data is not replicated to the remote database because the remote database is read-only." Claim 44 is therefore patentable over the applied references for this additional reason.

L. Claims 25-27 and 29-31: Umen does not suggest displaying at a user processor and subsidiary user processor which are operative to display a clinical trial protocol, a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task (Issue 3)

Umen does not suggest displaying at a user processor and subsidiary user processor which are operative to display a clinical trial protocol, a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task, as asserted by the Examiner in the non-final Office Action on page 17, third paragraph, and on page 20, third paragraph. Umen merely displays a tabular list of protocols, with none of the protocols indented. (See Umen, col. 10, lines 23-31.)

The Examiner responds on page 15 of the final Office Action by stating that Umen teaches this feature with Umen's statement that a management user interface "displays a tabular list 66 of protocol and results details" (col., 10, line 26). However, this statement does not include displaying a list of visits in sequence that form the protocol, with minor tasks that make up a major task

indented under the major task, as required by the claim. Claims 25-27 and 29-31 are therefore patentable over the applied references for this additional reason.

M. Claims 10 and 45: None of the applied references suggests the program automatically indicating the completion of a common major task in separate protocols when all of the minor related tasks are completed (Issues 3 and 4)

None of the applied references suggests a program that automatically indicates the completion of a common major task in separate protocols when all of the minor related tasks are completed, as asserted by the Examiner in the non-final Office Action on page 19, paragraph 3, and on page 21, third full paragraph. Colon merely discusses updating modified prescription data; there are no major or minor tasks disclosed. Umen discusses integrating data from more than one study, but again, there is no discussion of major and minor tasks, not to mention an indication of completion of a common major task in separate protocols. Edelson does not disclose anything close enough to this feature upon which to even comment here.

The Examiner responds on page 15 of the final Office Action by stating that Edelson teaches this feature with Edelson's disclosure that the "system also provides, for example in the patient's history record, notification from a pharmacy, or from a drug benefit plan linked to the pharmacy, of fulfillment of a prescription" (col. 27, lines 47-50). This quote from Edelson does not appear to bear any relation to the cited feature, and thus clearly can not teach or suggest the feature. Claims 10 and 45 are therefore patentable over the applied references for this additional reason.

N. Prior Art Rejections (Issues 1-4)

The Examiner has made a substantial number of assertions throughout the 19-page final Office Action dated February 6, 2004, particularly with regard to the how the applied references allegedly read on the pending claims. Applicant has responded to as many of these assertions as

practical. The lack of an explicit response to any of these assertions should not be deemed as an implied admission by Appellant of the assertion's merits.

O. Claims 35 and 36 are sufficiently definite (Issue 5)

The Examiner alleges that Claim 35, which recites "a plurality of user processors located at different clinical trial sites in the geographical area in which the main processor and main database are located," and Claim 36, which recites "a plurality of subsidiary processors and subsidiary databases each located in respective geographical areas that are different from the geographical area in which the main processor and main database are located" are indefinite because the geographical boundaries are unclear. The Examiner further states on page 16, last paragraph, of the final Office Action that "a 'geographical area' can exist around a cubicle, around a room, ... around a country, etc."

Claims 35 and 36 are not indefinite. "Breadth of a claim is not to be equated with indefiniteness." M.P.E.P. § 2173.04 (citing *In re Miller*, 441 F.2d 689, 169 U.S.P.Q. 597 (CCPA 1971)). Although these claims do not recite specific geographical boundaries, it is clear that in claim 35 the user processors are located in the same geographical area in which the main processor and database are located, and in claim 36 the subsidiary processors and databases are located in geographical areas that are different from the one in which the main processor and database are located. Thus, Claims 35 and 36 are sufficiently definite.

IX. CONCLUSION

Appellants further respectfully request that the application be remanded to the primary Examiner with an instruction to withdraw the § 112 and 103 rejections and pass the case to allowance.

Please charge any fee, except for the Issue Fee, that may be necessary for the continued pendency of this application to our Deposit Account No. 04-0100.

Dated: March 29, 2004

Respectfully submitted,

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APPENDIX

Claim 1 (amended): A clinical trial management system comprising:

a main database of information concerning prior clinical trials and resources available to conduct future clinical trials, the information concerning prior clinical trials being at least in part in the form of a protocol of (a) scheduled visits of a test subject to a treatment site, (b) measurement of prescribed physical attributes of the subject during the visits and (c) administration of at least one prescribed medical product to the subject during the visit to determine over time the subject's response thereto, the protocol of a prior clinical trial being stored in said main database in the form of a software template;

a main processor controlling access to said main database; and

at least one user processor in communication with said main processor to negotiate access to said main database, said user processor and main processor running a program that designs and tracks at said user processor of a clinical trial through access by said user processor to at least one software template in said main database and modification of the template for formulating a new clinical trial.

Claim 2 (original): The clinical trial management system of claim 1 further comprising:

a subsidiary database;

a subsidiary processor controlling access to said subsidiary database, said subsidiary processor being in communication with said main processor to controlling replication of a portion of the data in the main database to said subsidiary database;

at least one subsidiary user processor in communication with said subsidiary processor, said subsidiary processor and subsidiary user processor running the program so as to permit the design and tracking at said subsidiary user processor of a clinical trial based on data in said subsidiary database.

Claim 3 (original): The clinical trial management system of claim 2, wherein said subsidiary processor, subsidiary database and subsidiary user processor are located in a certain geographical location remote from the location of said main database and said main processor; and

wherein the portion of data replicated to said subsidiary database relates to clinical trials in said certain geographical location.

Claim 4 (original): The clinical trial management system of claim 3 wherein the portion of data in said subsidiary database includes at least one template of a clinical trial protocol previously created according to requirements prevalent in the certain geographical location.

Claim 5 (original): The clinical trial management system of claim 3,

wherein the portion of data in said subsidiary database can be altered by said subsidiary user processor and the data in the main database can be altered by said user processor; and

wherein said main processor and said subsidiary processor periodically operate to synchronize the replicated and changed data at said main database and said subsidiary database, with changes at said main database predominating over changes at said subsidiary database.

Claim 6 (original): The clinical trial management system of claim 1 wherein said main processor and main database are in an organizational environment which includes other databases with specialized information useful in formulating clinical trials; and

further including a communications link with said other databases and means for replicating selected portions of the data in the other databases into the main database.

Claim 7 (original): The clinical trial management system of claim 6 wherein the other databases are one of a human resources database of personnel and location information, a finance database of budget authorization and cost information and a clinical supplies database of information on the availability of various clinical medical products.

Claim 8 (original): The clinical trial management system of claim 1 further including a display at the user processor which is operative to display the clinical trial protocol as a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task.

Claim 9 (original): The clinical trial management system of claim 8 wherein said users processor can used to input information concerning completion of tasks in the protocol, and the display is updated to show progress of the trial.

Claim 10 (original): The clinical trial management system of claim 9 wherein the program automatically indicates the completion of a major task when all of its minor related tasks are completed.

Claim 11 (original): The clinical trial management system of claim 1 wherein the program is in the form of modules.

Claim 12 (original): The clinical trial management system of claim 11 wherein the program includes a reports module that generates reports of the status of the trial for presentation on the display.

Claim 13 (original): The clinical trial management system of claim 11 wherein the program includes a reports module that generates messages to personnel concerning actions to take to advance the trial.

Claim 14 (original): The clinical trial management system of claim 13 wherein at least one of the messages is to a provider of clinical supplies for the trial to inform it of the medical products needed for the trial.

Claim 15 (original): The clinical trial management system of claim 3 wherein the program includes a site management module for indicating the conditions at the certain geographical location, including the portion of any protocol to be carried out in that geographical location.

Claim 16 (original): The clinical trial management system of claim 15 wherein information about the completion of tasks in the protocol at the certain geographical location are entered by the subsidiary user processor in the subsidiary database, and the site management module updates the portion of the protocol related thereto.

Claim 17 (original): The clinical trial management system of claim 1 further including a portable processor running the program, said portable processor operating with said main processor to transfer to the portable processor a copy of a portion of the main database related to a site for the clinical trial in a certain geographical area, said main processor locking the portion of the main database that was copied, said portable processor receiving information about the completion of tasks in the protocol at the certain geographical area and modifying the copy as a result thereof, and said portable processor operating with said main processor to transfer to and update the main database with the modified copy of the data and to unlock that portion of the main database.

Claim 18 (withdrawn)

Claim 19 (amended): A clinical trial management system comprising:

a main database of information concerning resources available to conduct clinical trials;

a main processor controlling access to said main database;

at least one user processor in direct communication with said main processor to negotiate access to said main database, said user processor and main processor running a program that designs

a clinical trial in the form of a protocol of tasks to be completed and tracks the completion of the tasks in the protocol at said user processor;

a subsidiary database;

a subsidiary processor controlling access to said subsidiary database, said subsidiary processor being in communication with said main processor to controlling replication of a portion of the data in the main database to said subsidiary database;

at least one subsidiary user processor in communication with said subsidiary processor, said subsidiary processor and subsidiary user processor running the program so as to design and track at said subsidiary user processor a protocol based on data in said subsidiary database.

Claim 20 (original): The clinical trial management system of claim 19,

wherein said subsidiary processor, subsidiary database and subsidiary user processor are located in a certain geographical location remote from the location of said main database and said main processor; and

wherein the portion of data replicated to said subsidiary database relates to clinical trials in said certain geographical location.

Claim 21 (original): The clinical trial management system of claim 20 wherein the portion of data in said subsidiary database includes at least one template of a clinical trial protocol previously created according to requirements prevalent in the certain geographical location.

Claim 22 (original): The clinical trial management system of claim 20,

wherein the portion of data in said subsidiary database can be altered by said subsidiary user processor and the data in the main database can be altered by said user processor; and

wherein said main processor and said subsidiary processor periodically operate to synchronize the replicated and changed data at said main database and said subsidiary database, with changes at said main database predominating over changes at said subsidiary database.

Claim 23 (original): The clinical trial management system of claim 19 wherein said main processor and main database are in an organizational environment which includes other databases with specialized information useful in formulating clinical trials; and

further including a communications link with said other databases and means for replicating selected portions of the data in the other databases into the main database.

Claim 24 (original): The clinical trial management system of claim 23 wherein the other databases are one of a human resources database of personnel and location information, a finance database of budget authorization and cost information and a clinical supplies database of information on the availability of various clinical medical products.

Claim 25 (original): The clinical trial management system of claim 19 further including displays at the user processor and subsidiary user processor which are operative to display the clinical trial protocol as a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task.

Claim 26 (original): The clinical trial management system of claim 25 wherein said user processors and subsidiary user processors can used to input information concerning completion of tasks in the protocol, and the display is updated to show progress of the trial.

Claim 27 (original): The clinical trial management system of claim 26 wherein the program automatically indicates the completion of a major task when all of its minor related tasks are completed.

Claim 28 (original): The clinical trial management system of claim 19 wherein the program is in the form of modules.

Claim 29 (original): The clinical trial management system of claim 27 wherein the program includes a reports module that generates reports of the status of the trial for presentation on the display.

Claim 30 (original): The clinical trial management system of claim 27 wherein the program includes a reports module that generates messages to personnel concerning actions to take to advance the trial.

Claim 31 (original): The clinical trial management system of claim 29 wherein at least one of the messages is to a provider of clinical supplies for the trial to inform it of the medical products needed for the trial.

Claim 32 (original): The clinical trial management system of claim 19 wherein the program running on said subsidiary user processor includes a site management module for indicating the conditions at the certain geographical location, including the portion of any protocol to be carried out in that geographical location.

Claim 33 (original): The clinical trial management system of claim 32 wherein information about the completion of tasks in the protocol at the certain geographical location are entered by the subsidiary user processor in the subsidiary database, and the site management module updates the portion of the protocol related thereto.

Claim 34 (original): The clinical trial management system of claim 19 further including a portable processor running the program, said portable processor operating with said main processor to transfer to the portable processor a copy of a portion of the main database related to a site for the clinical trial in a certain geographical area, said main processor locking the portion of the main database that was copied, said portable processor receiving information about the completion of tasks in the protocol at the certain geographical area and modifying the copy as a result thereof, and said portable processor operating with said main processor to transfer to and update the main database with the modified copy of the data and to unlock that portion of the main database.

Claim 35 (original): The clinical trial management system of claim 19 wherein there are a plurality of user processors located at different clinical trial sites in the geographical area in which the main processor and main database are located.

Claim 36 (original): The clinical trial management system of claim 19 wherein there are a plurality of subsidiary processors and subsidiary databases each located in respective geographical areas that are different from the geographical area in which the main processor and main database are located.

Claim 37 (original): The clinical trial management system of claim 36 wherein there are a plurality of subsidiary user processors located in each geographical area in which a subsidiary processor and subsidiary database are located, said plurality of subsidiary user processors being connected to the subsidiary processor in their respective geographical area.

Claim 38 (original): The clinical trial management system of claim 37 in which the geographical areas are countries.

Claims 39-42 (withdrawn)

Claim 43 (amended): A clinical trial management system comprising:

a main database of information concerning resources available to conduct clinical trials;

a main processor controlling access to said main database;

at least one user processor in direct communication with said main processor to negotiate access to said main database, said user processor and main processor running a program that designs a clinical trial and the input of information with regard to the completion of tasks forming a protocol for the clinical trial and tracks the completion of the tasks at said user processor, a portion of said program printing forms determined by the data in the system.

Claim 44 (original): The clinical trial management system of claim 43,

further including a subsidiary processor, subsidiary database and subsidiary user processor located in a certain geographical location remote from the location of said main database and said main processor; and

wherein a portion of data in the main database is replicated to said subsidiary database and relates to clinical trials in said certain geographical location.

Claim 45 (original): The clinical trial management system of claim 19 wherein the system manages a plurality of clinical trials with separate protocols, at least some of the separate protocols having major tasks made up of a plurality of minor tasks that are common to them, and wherein the program automatically indicates the completion of a common major task in the separate protocols when all of the minor related tasks are completed.